Attachment 5

MAR 16 2007

510(k) Summary of Safety and Effectiveness

I. General Information

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 § 807.92.

Establishment:

- Address: BD Medical – Pharmaceutical Systems
  1 Becton Drive
  Franklin Lakes, NJ 07417-1885
- Registration Number: 2243072
- Contact Person: Aileen Gilbert
  Senior Regulatory Affairs Specialist
  Telephone No.: 201-847-7197
  Fax No.: 201-847-7040
  E-Mail: aileen_gilbert@BD.com
- Date of Summary: February 14, 2007

Device

- Trade Name: BD Hypoint™
- Common Name: Hypodermic Needle
- Classification Name: Single Lumen Hypodermic Needle
- Classification: Class II
- Performance Standards: None Established under 514 of the Food, Drug and Cosmetic Act

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II. Safety and Effectiveness Information Supporting Substantial Equivalence

- Device Description

The BD Hypoint™ Needle is a hypodermic single lumen needle, designed for use with syringes and injection devices for general purpose fluid injection / aspiration. The BD Hypoint™ Needles are offered in various gauge sizes and needle lengths. The BD Hypoint™ Needle is sterilized by gamma irradiation (Cobalt-60). The BD Hypoint™ Needle is Non-Toxic, Non-Pyrogenic, Disposable and intended for Single Use.

- Intended Use

The BD Hypoint™ Needle is intended for use with syringes and injection devices for general purpose fluid injection / aspiration.

- Synopsis of Performance Study Results

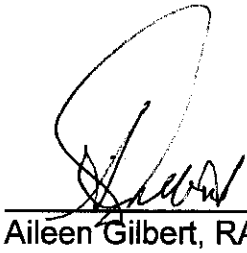
Bench testing was performed to confirm the BD Hypoint™ Needle equivalence to the predicate device. The need for clinical analysis of the BD Hypoint™ Needle was assessed by the BD Medical Pharmaceutical Systems, Medical Affairs Department and with consideration to the extensive market history of this device outside of the United States, with the same intended use, the substantial device and design history on these other markets was the justification for not performing a clinical investigation for this device modification submission in the U.S. Therefore, based on the performance test results, the BD Hypoint™ Needle is safe and effective when used as intended.

III. Predicate Device Summary Table

- Substantial Equivalence

Based on comparison of the device features, materials, intended use and performance, the BD Hypoint™ Needle has shown to be substantially equivalent to the commercially available predicate device indicated in the table below. The predicate device, 510(k) number, and clearance date are also identified in the table below.

Manufacturer	Predicate Device	510(k) Number	Clearance Date
Becton Dickinson and Company	BD PrecisionGlide™ Needle	K021475	July 19, 2002



Aileen Gilbert, RAC
Senior Regulatory Affairs Specialist
BD Medical – Pharmaceutical Systems
Becton Dickinson and Company

2/14/2007
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Aileen C. Gilbert
Senior Regulatory Affairs Specialist
Becton Dickinson & Company
1 Becton Drive
Franklin Lakes, New Jersey 07417-1889

MAR 16 2007

Re: K070440
Trade/Device Name: BD Hypoint™ Needle
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: February 14, 2007
Received: February 16, 2007

Dear Ms. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE

510(K) NUMBER (IF KNOWN): K070440

DEVICE NAME: **BD Hypoint™ Needle**

INDICATIONS FOR USE:

The BD Hypoint™ Needle is intended for use with syringes and injection devices for general purpose fluid injection / aspiration.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

PRESCRIPTION USE X OR OVER-THE-COUNTER USE _____

(PER 21 CFR § 801.109)

(OPTIONAL FORMAT 1-2-96)

K070440